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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/333,159	06/14/1999	SEAN A. MCCARTHY	10147-6	3785

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02/14/2003

INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS
75 SIDNEY STREET
CAMBRIDGE, MA 02139

EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/14/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/333,159

Applicant(s)

MCCARTHY ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 12 and 24-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66 is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 12, 26-28, 30-34 and 36-65 is/are rejected.
- 7) ☒ Claim(s) 2, 24, 25, 29 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED OFFICE ACTION

The request filed on 25 November 2002, paper No. 15, for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/333,159 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment in paper No. 16, filed on 25 November 2002 is acknowledged and entered. Following the amendment, claims 1-5, 7, 12, 24-33 and 35-40 are amended, and the new claims 41-66 are added.

Currently claims 1-7, 12, and 24-66 are pending, and under consideration.

At pages 1-2, and 12 of the response, Applicants indicate that agreement was reached during the 15 October 2002 interview regarding subject matter that would be considered allowable. The Examiner would like to clarify that even though the subject matter of the invention was discussed during the interview, however, no agreement of any kind was reached because the claims were not in condition for allowance for the reasons addressed in the interview summary, paper No. 13.

Withdrawal of Objections and Rejections:

The objection of claims 38 and 40 under 37 C.F.R. §1.75(b) as being duplicate claims is withdrawn in view of applicant's amendments.

The scope rejection of claims 1, 3-7, 12, 24-26, 30, 32-34, and 36-38 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendments.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 33, 38, 40 and 43-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "*the consecutive* amino acid residues" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 43 is indefinite for the limitation of "encodes a variant in part e). The preamble of the claim recites "i) encodes an immunogenic portion of the protein having the amino acid sequence encoded by SEQ ID NO:46", which specifies the sequence of the protein. As such, the nucleic acid cannot, meanwhile, encode a variant of the amino acid sequence encoded by SEQ ID NO:46, as claimed in part e). Claims 54 and 65 are similarly indefinite.

Claim 65 recites the limitation "the polypeptide" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The remaining claims are rejected for depending from an indefinite claim.

Note: the term "immunogenic portion" used in the claims, claims 41-43 for example, is interpreted as reading on any fragments capable of eliciting immune response specific to the polypeptide having the amino acid sequence encoded by SEQ ID NO:45 or 46.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, 28 and 31 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record in the previous Office Actions, paper No. 7, at page 6, and paper No. 9, at page 3.

The claims are directed to the nucleic acid fragments of SEQ ID NO:45 or 46 (claims 27 and 28), or the nucleic acid encoding small fragments of the amino acid encoded by SEQ ID NO:46 (claim 31), wherein the nucleic acids encode a polypeptide exhibiting lipase activity. As addressed previously, given the fact that the TANGO294 polypeptide molecule has 423

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amino acid residues, a fragment of 25 amino acids (claim 31, for example) is unlikely to possess the lipase activity. Additionally, the art generally does not acknowledge that a small portion of a large enzyme molecule, for example, 25 amino acid residues in size, would possess enzymatic activity. The specification provides neither guidance nor working examples regarding such functional fragments. Therefore, it is unpredictable such a small fragment would possess the biological property, thus undue experimentation would be required prior to using the claimed invention.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 12, 26, 30, 32, 33, 34, 36-44, 47, 51, 53, 54, 56-62, 64 and 65 are rejected under 35 U.S.C. 102(a) as being anticipated by Blanchard et al., US 5,807,726.

Blanchard discloses a nucleic acid (SEQ ID NO:2) encoding a polypeptide (SEQ ID NO:3), which is a dog gastric lipase (column 2, lines 29-37). The referenced nucleic acid sequence comprises nucleotides 125-1221 of SEQ ID NO:46 of the present invention with 62.8% sequence similarity, and has 84.7% sequence similarity within the coding region for amino acids 37-407 of SEQ ID NO:47 of the instant invention (see appended computer printout of sequence search results). Blanchard's nucleic acid, therefore, anticipates claims 1, 26, 30, 32, 33, 39, 43, 44, 47, 51, 53, 54 as being a nucleic acid hybridizing to SEQ ID NO:46, and encoding a variant of SEQ ID NO:46, wherein the encoded polypeptide exhibits lipase activity (claim 1, part e, and claims 32 and 39), a nucleic acid comprising a fragment of SEQ ID NO:46 (claims 26 and 47), a nucleic acid encoding a polypeptide comprising a fragment or immunogenic portion (amino acids 106-117) of the sequence encoded by SEQ ID NO:46, and/or hybridizing to SEQ ID NO:46 (claims 30, 33, 43, part e), 44, 51, 53, 54). Further, Blanchard teaches said nucleic acid comprising heterologous sequence (column 4, lines 37-41), a vector comprising said nucleic acid

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(column 4, lines 50-54), a host cell thereof including a mammalian cell, a non-human mammalian cell, a prokaryotic cell (column 4, the last paragraph, and column 5, the first paragraph), and a method for producing the polypeptide (column 6, lines 60-67, and column 7, lines 1-10). Thus, the reference also anticipates claims 3-7, 12, 34, 36, 37, 38, 40, 41, 42, 56-62, 64, 65.

Claims 1, 3-7, 12, 26, 30, 32, 33, 34, 36-44, 47, 51, 53, 54, 56-62, 64 and 65 are also rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (J. Biol. Chem., 1991, 266: 22479-84).

Anderson discloses a nucleic acid encoding a polypeptide of human lysosomal acid lipase (Figure 4). The referenced nucleic acid sequence comprises nucleotides 39-1241 of SEQ ID NO:46 of the present invention with 65.3% sequence similarity, and encodes amino acids 2-409 of SEQ ID NO:47 of the instant invention with 83% sequence similarity (see appended computer printout of sequence search results). Anderson's nucleic acid, therefore, anticipates claims 1, 26, 30, 32, 33, 39, 43, 44, 47, 51, 53, 54 for the same reasons addressed above. Further, Anderson teaches a vector comprising said nucleic acid, a host cell thereof including a mammalian cell, a non-human mammalian cell, a prokaryotic cell, and a method for producing the polypeptide (page 22480, the last paragraph of the left column,). Thus, the reference also anticipates claims 3-7, 12, 34, 36, 37, 38, 40, 41, 42, 56-62, 64, 65 for the same reasons above.

Conclusion:

Claim 66 is allowable.

Claims 2, 24, 25, 29 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink that reads "Lorraine Spector". The signature is written in a cursive style with a large, looping initial "L".

**LORRAINE SPECTOR
PRIMARY EXAMINER**

DJ

1/30/03